

DEC 8 9 2002

Re: Patent Application for Dornelas **Date:** Dec 2, 2002
Serial 09/578,194 **Art Unit:** 1635
No.:
Filed: 05/24/00 **Examiner** Schmidt, M
:
For: Modulation of Storage Organs **Action:** Petition from requirement for restriction

To: The Commissioner of Patents and Trademarks, Washington, DC 20231

Petition from requirement for restriction

This Petition is filed prior to appeal and thus should be timely filed. The Examiner requested in the initial paper of August 13, 2001 an election of the two alleged inventions one being to claims 1-12 and 15-24 concerning sense and the second invention being directed to claims 1-24 concerning antisense. The applicant elected claims 1-24 concerning antisense with traversal. To the extent that the earlier paper from applicant selected the other invention the applicant asked that that election be ignored and the election to the second invention being directed to claims 1-24 concerning antisense be employed.

Additionally the applicant was requested to elect an invention directed to a species of genes from the ASK genes of Group II. The applicant elected, with traverse, the dzeta Ask gene of Group II.

Further the applicant was requested to elect an invention directed to a species of plant for search and examination of the invention. The applicant elected the plant *Arabidopsis* with traverse.

The applicant in an effort to have the restriction requirement removed amended claim one of the application with the first response. The Examiner did not consider this amendment sufficient to remove the restriction requirement. Therefore, in the second response the applicant deleted the amendment that was previously submitted. The Examiner held that the election was final and that the invention was limited to an ASKdzeta antisense in *Arabidopsis*.

To restrict the claims and cause an election the Examiner has to show that the inventions are INDEPENDENT.

The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process. The specification clearly indicates that more than one of the ASK gene group II, is useable together. The Examiner has not shown that the alleged ASK gene Group II are actually independent inventions under this criteria. In the action making the restriction final the Examiner indicated that the different ASK genes were considered independent inventions based on their distinct and unique nucleic acid sequence and because sense gene and the antisense gene are two different sequences these were restricted. The applicant disagrees. Further the Examiner in the last office action stated that the administration of sense and antisense would have a different consideration for the plant development and thus a serious search burden was rendered. Again the Applicant disagrees. The administration of a cosuppression construct whether in the sense orientation or in the antisense orientation is administrated in the same way and can be the same sequence in reverse order and additionally and most seriously both are cosuppressing i.e. causing the suppression of the native genes activities.

The Examiner must also show that the inventions are patentably distinct and the criteria for restriction between patentably distinct inventions are:

- (A) The inventions must be independent or distinct as claimed; and
- (B) There must be a serious burden on the examiner if restriction is required.

The Examiner has not shown that these inventions (which are related as disclosed in the specification) are either independent or distinct as claimed. In fact in the final office action the Examiner indicates that the ASK Gene Group have a high level of homology, sharing significant nucleic acid sequence but the genes are not identical and

the differences between them render them unique species. Then the Examiner states that the sense and antisense gene are two different sequences are thus restricted. The *prima facie* burden of the Examiner has not been met by alleging that these claims are directed to inventions which are species.

The applicant is not suggesting that if these inventions are directed to species that the species are not patentably distinct. However, the Examiner alleging that the inventions which are directed to different plants and genes as claimed, are inventions to species is simply not sufficient to make a case that these plants and gene are inventions to separate species. And the second part of the requirement to make a restriction has simply not been shown. The Examiner has not shown that the inventions are in separate search classifications and that it would be a **SERIOUS BURDEN** to search these alleged inventions. In fact the Examiner has pointed out the ASK Gene Group have a high level of homology, sharing significant nucleic acid sequence **but the genes are not identical**. If the genes were identical there would of course be only one gene thus one invention. The Examiner's reply indicates that the Examiner is not looking at the correct considerations for determining whether a restriction is required. The applicant argues that under the Commissioner's position in the MPEP quoted below that the restriction is inappropriate and should be removed. The statute that gives the PTO authority to restrict is as follows: The basis for restriction and double patenting practices is found in the following statute:

35 U.S.C. 121 Divisional applications.

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.... In light of this the PTO has instituted within the CFR section 1.142 the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). and MPEP 803.04 which states:

Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

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It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined.

Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

The Examiner in the first restriction appears to indicate that either a gene species has to be elected or a plant species has to be elected. The Applicant was very surprised in the Examiner's final statement on the restriction that in fact the Examiner intended that the claim be limited to a single specie of gene and a single specie of plant. It appeared through out the office actions that the Examiner was implying that either a gene specie or a plant specie had to be selected, not that both a plant and a gene had to be elected. However in the final decision on the restriction, the Examiner is in fact arguing that not one but both restrictions to a specific gene "species" and to a plant "species" must be made and according to the Examiner was made.

The applicant believes that the invention is a process and the material that it is used in the process should not be limited to a specific "species" of plants, as the different plant material does not require different processes. The Examiner indicates that the gene in the application is native to *Arabidopsis* and therefore if any other plant were used in the process a different native gene from that plant would be employed thus under 806.04(f) the Examiner alleged the claim to the process would be mutually exclusive for each plant material. The applicant disagrees. Although the gene native to the plant could be used it is not necessary with the homology that is shown in the application between plants genes to use the native gene from the plant used in the process. The *Arabidopsis* gene could be employed in the process regardless of plant species employed due to the homology of these genes across plants. Additionally the second claim points out where the section of the gene that carries the homology is located and its use in the construct. Thus the Examiner's indication or suggestion that the native gene for each plant may be

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used is not sufficient reason to make the restriction to *Arabidopsis* as a plant species necessary as there are not MUTUALLY EXCLUSIVE CHARACTERISTICS in the method when different plant species are employed.

806.04(f) Claims Restricted to Species, by Mutually Exclusive Characteristics

Claims to be restricted to different species must be mutually exclusive.

The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first. This is frequently expressed by saying that claims to be restricted to different species must recite the mutually exclusive characteristics of such species.

With the exception of claim 24, which is directed to a product, the rest of the claims are directed to a process, which can be employed in any number of plants without modification of the process. The applicant hereby petitions the Commission to review the Examiner's restriction requirement and respectfully requests in light of the applicant's arguments that the Commission reconsider the restriction requirement and remove such restriction requirement.

Respectfully submitted,

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CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

I hereby certify that attached is a postcard and this **Petition from requirement
for restriction**

is which being deposited on Dec 2, 2002 and is addressed to the Commissioner of
Patents and Trademarks, Washington, DC 20231.

John P. Hartman
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